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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 15

Application Number: 09/391,762
Filing Date: September 08, 1999
Appellant(s): WEADOCK ET AL.

Salvatore J. Abbruzzese
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 31, 2001.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences that will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. However, appellant has reordered the rejections in a manner that is hard to follow by not keeping alternative 102/103 rejections together and not following the order of the final office action. The Examiner has returned the order of the issues to the following:

1. Whether claims 13-18 constitute improper recapture under 35 USC 251.

2. Whether claim 13 is anticipated under 35 USC 102(e) by Jernberg (US 5,290,271).

3. Whether claim 13 is obvious under 35 USC 103(a) by Jernberg (US 5,290,271) alone.

4. Whether claims 1-8 and 11-18 are anticipated under 35 USC 102(b) by Tran et al (article).

5. Whether claims 1-8 and 11-18 are obvious under 35 USC 103(a) by Tran et al (article) in view of Okita (US 4,193,138).

6. Whether claims 1-10, 13-16, and 18 are obvious under 35 USC 103(a) over Hoffman, Jr. et al (US 5,197,977) in view of Okita et al (US 4,193,138).

7. Whether claims 1-8, 11, 13-16, and 18 are obvious under 35 USC 103(a) over Alonso (US 5,037,377) in view of Okita (US 4,193,138).

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-12 and 13-18 do stand or fall together and provides a reason why patentability should be predicated on independent claims 1 and 13.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,665,114	Weadock et al	09-1997
5,290,271	Jernberg	03-1994
4,842,575	Hoffman, Jr. et al	6-1989
4,193,138	Okita	03-1980
5,037,377	Alonso	08-1991

Tran et al "Plasma Modification and Collagen Binding to PTFE Grafts", Journal of Colloid and Interfacial Science, Vol. 132, No. 2, October 15, 1989, pp. 373-381.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 13-18 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue, which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that Appellant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Present claims 13-18 are improper for a reissue application because they attempt to recapture subject matter surrendered in order to overcome a prior art rejection. Specifically, during the pendency of the patented file 08/289,790, the language "filled with fluid which solidifies and is crosslinked to form" and "said material being insoluble at a pH of about 7.4" was added in order to overcome a prior art rejection. Therefore, it is improper to attempt to recapture this subject matter via claims 13-18 in the present reissue application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Appellant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Appellant for patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Jernberg (US 5,290,271), or alternatively under 35 U.S.C. 103(a) as being unpatentable over Jernberg (US 5,290,271) alone. Jernberg anticipates the claim language wherein the microparticles are the precipitated composition as claimed since they are precipitated out of a fluid suspension onto and into the expanded polytetrafluoroethylene substrate; see the entire document. Precipitation can be simply a removing of suspended solid particles out of liquid suspension of those particles, and thus, the claim language is fully met with this interpretation.

Alternatively, since the process limitations are not explicitly set forth in Jernberg, one could interpret the claim as not being fully met. However, since it appears that at least a substantially identical product is produced thereby, it is the Examiner's position that the claimed product is at least clearly obvious over Jernberg alone; see MPEP 2113 which is incorporated into this rejection by reference thereto.

Claims 1-8 and 11-18 are rejected under 35 U.S.C. 102(b) as anticipated by Tran et al (article entitled "Plasma Modification . . . ") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tran et al (article entitled "Plasma Modification . . . ") in view of Okita (US 4,193,138). Tran et al (article) anticipates the claim language wherein GORTEX grafts are synonymous with expanded polytetrafluoroethylene grafts that have node and fibrils as claimed. The collagen is precipitated out of the Vitrogen solution as a suspension onto the graft substrate at a particular pH and temperature such that the crosslinking reaction can take place; see the entire document.

Alternatively, one may not consider Tran et al (article) an anticipating patent because it does not explicitly disclose the fibril and node structure as set forth in the present claims. However, the Okita teaches that such fibril and node structure is known to the same art and indirectly that GORTEX is an expanded polytetrafluoroethylene material with nodes and fibrils; see the entire document, especially the figures and column 1, lines 26-41. Hence, it is the Examiner's position that it would have been obvious to use the graft of Okita as the substrate of Tran et al for the same reasons that Okita uses the same in the invention thereof and so that an impregnatable substrate material can be used as a better means to hold the collagen to the graft.

With regard to claim 17, Appellant is directed to page 375, second column, lines 1-9 where phosphate buffer saline is used to maintain the pH close to 7.00 that is also □about 7.4" as claimed.

Claims 1-10, 13-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman Jr. et al (US 5,197,977) in view of Okita et al (US 4,193,138). Hoffman Jr. et al meets the claim language by disclosing a vascular graft which is sealed by a precipitate of collagen and solidified by crosslinking but fails to disclose the expanded PTFE substrate as claimed; see the entire document. Okita, however, teaches that it was known to the art to use expanded PTFE as a substrate or implant material in order to provide an inert graft material; see the entire document. Hence, it is the Examiner's position that it would have been obvious to use the Okita base material or substrate as the substrate of Hoffman, Jr. et al so that the inert and advantageous properties envisioned by Okita can be utilized in the Hoffman, Jr. et al invention.

Claims 1-8, 11, 13-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alonso (US 5,037,377) in view of Okita (US 4,193,138). Alonso discloses many types of porous substrates for use therewith but fails to disclose the use of expanded PTFE, which inherently has the node and fibril structure recited in claims 1 and 13, as the substrate material; it is noted that soluble collagen of Alonso is made insoluble by crosslinking it and that it is insoluble at a 7.4 pH because 7.4 is the pH of the crosslinking solution and the crosslinking solution does not dissolve the collagen material; see the entire document. Okita, however, teaches that it was known to use

expanded PTFE as a substrate and graft material in order to provide an inert graft material; see the entire document. Hence, it is the Examiner's position that it would have been obvious to use the Okita base material or substrate for the base or substrate of Alonso so that inert and advantageous properties envisioned by Okita can be utilized in the Alonso invention.

(11) Response to Argument

Issue 1

Appellant traverses the 35 USC 251 rejection by stating that recapture is permitted when the claim is narrowed so as to remove it from trying to obtain surrendered subject matter. Upon careful consideration of the Appellant's remarks and the file wrapper histories of the cases involved, the Examiner came to the conclusion that the recapture that Appellant is attempting is impermissible.

Since the present claims 13-18, which broaden the scope of the patented claims in some regard, were filed within 2 years of the patent date, Appellant is within the statute in attempting to broaden the claims. The broadening is based upon the scope of the claims granted in the patent; present claims 1-12 are of the same scope as the patented claims 1-12.

Appellant argues that the present claim 13 does not impermissibly recapture surrendered subject matter because claim 13 has been narrowed in some aspects such that it is sufficiently distinct from patented claim 1 so as to not claim the surrendered subject matter. However, the Examiner posits that the added limitations do not sufficiently distinguish it from the surrendered claim.

In particular, Appellant is directed to MPEP 1412.02 and Examples A and particularly B thereof which closely match the present fact scenario. In addition, Appellant is directed to review the interview summary record (Paper No. 17) of the patented file which states that "**Agreed on language that distinguishes over Jernberg and the other arts of record. Claim 1 has been amended to include allowable language.**". Examiner Brittingham's summary of the interview was never contradicted or questioned by the Appellant upon receipt thereof and the application subsequently issued.

Along with the interview, three specific changes were made to claim 1 which put the claims in condition for allowance. The amendments to claim 1 on February 27, 1997 were as follows:

> In claim 1, on line 6, the language ----filled with fluid which solidifies and is crosslinked to form---- was inserted after "pores" and the word "containing" was deleted on this same line.
>
> In claim 1, on line 6, after "solid", ---precipitate of a--- was inserted.
>
> In claim 1, on line 8, after "origin", ----said material being insoluble at a pH of about 7.4---- was inserted.

It is the Examiner's position that claim 13, which is similar to patented claim 1 except that it is broader in some aspects and narrower in another, is attempting to eliminate or broaden these limitations without significantly or sufficiently limiting claim 13 in other aspects.

Appellant argues that claim 13 is broader in some aspects but narrower than patented claim 1 in other aspects. In response, the Examiner the present broadening,

which (1) leaves out the pH value, (2) only substantially fills the pores with a solidified material, (3) does not claim that the composition is crosslinked, and (4) does not state that the composition is "solid", is not acceptable because these limitations were relied upon to put the claims in allowable form.

In response to the Appellant's argument that the narrowing aspects of claim 13 remove it from a recapture scenario, the Examiner asserts that both temperature and cellular attachment are broad limitations as they are set forth. In particular, the temperature limitation is based upon a process of making condition in this product claim. For this reason, it is not significantly limiting. Furthermore, the cellular attachment limitation is a statement of intended use merely stating the purpose of the biodegradable composition. In other words, it is not clearly related to any particular structure of the composition. Furthermore, the pore filling limitation is actually broader than patented claim 1 because present claim 13 sets forth "substantially fills" instead of "fills"; see MPEP 2173.05(b) which is incorporated herein by reference. For this reason, the narrowing limitations are not considered significant.

In response to the traversal stating that the *Whittaker Corp. v. UNR Industries, Inc.* decision allowed reissue claims broader in certain aspects but narrower in others, the Examiner respectfully disagrees and takes the position that this case only decided one issue, that is, whether the reissue patent claims differ materially from the claims that were surrendered to obtain the original patent; see page 1744 of the decision. It is not seen, in this decision, where reissue claims can broadened and still avoid the recapture doctrine. Nonetheless, that is not the particular issue here where patentee

clearly surrendered subject matter and is attempting to recapture that same subject matter in this reissue application.

Furthermore, there is additional evidence of record which suggests that recapture of surrendered subject matter is being attempted. Specifically, the reissue declarations filed November 26, 1999 state that the purpose of the reissue was to broaden the pH limitation. Since the pH value was added to overcome a ground of rejection, the broadening of it at this point is considered to result in recapture.

Finally, Appellant argues that there is a difference in the biodegradable composition since it substantially fills the pores. However, upon reviewing original claim 5 of the present application, it is clear that this is not true. Claim 5 states that the "biodegradable material substantially fills said pores to render substrate blood-tight."

Issue 2

Appellant argues that there is no disclosure that the microparticles fill pores and provide a site for cellular attachment. However, cellular attachment is a naturally occurring process that will occur on most materials in the short length of time. Furthermore, since the same substrate and biodegradable material is used in both the Jernberg disclosure and the disclosed and claimed present invention, it follows that that a site for cellular attachment would be provided by Jernberg to the extent required by the present claims.

Issue 3

Jernberg, as stated in the rejection, discloses that the microparticles, which are the precipitated composition as claimed, are precipitated out of a fluid suspension onto

and into the expanded polytetrafluoroethylene substrate; see the entire document. Precipitation can be simply a removing of suspended solid particles out of liquid suspension of those particles, and thus, the claim language is fully met with this interpretation.

In addition, Jernberg's microparticles are placed within the pores and "substantially fill[s]" them to the extent this language can be given weight; see column 3, lines 44-60 where the particles are disclosed as being placed within the pores. Moreover, "substantially" is a broad term; see MPEP 2173.05(b) which is incorporated herein by reference thereto.

Furthermore, this process, to the extent it can be given weight in a product claim (see MPEP 2113), is done at a pH and temperature which allows it to be done. Thus, the claim language in that regard is met. In addition, since the graft with microparticles, would not prevent cellular attachment, it also would function to be a site for cellular attachment to the extent that this language can be given weight. For these reasons, claim 13 is fully met by Jernberg such that the rejection thereon is maintained.

In response to the argument that the Jernberg material is not insoluble as claimed, the Examiner notes that polymers, such as collagen, which are insoluble and biodegradable fully meet the claim language.

Appellant also argues that the microcapsules of Jernberg quickly degrade such that they would not allow cellular attachment. However, Jernberg clearly allows variables grades of materials for variable control of the release of drugs; see column 4, lines 27-48. For this reason, the argument is considered unpersuasive since Jernberg

clearly allows a variation in the materials used. Moreover, the materials used by Jernberg are the same ones used by Appellant.

Issue 4

Appellant argues that Tran et al (article) does not disclose porous PTFE as claimed. However, the Examiner posits that GORTEX is a type of expanded PTFE because this tradename refers precisely to the expanded form of PTFE.

The Examiner proposed showing that an **inherent feature** of GORTEX is that it is by definition expanded PTFE. Thus, the Examiner has provided a copy of US Patent 5,207,709 which describes GORTEX as expanded PTFE; see column 3, lines 12-24.

> "*Expanded PTFE is sold under the trade name 'GORTEX' and is a fibrous material which . . .* "

Since GORTEX is merely understood as denoting expanded PTFE, the Examiner need not make the rejection as a combination with Picha.

Appellant argues that the biodegradable carrier of Tran would degrade quickly to release the drug. However, the Examiner posits that it is not necessary for the carrier to degrade in order to release the drug. For this reason, the argument that the carrier must degrade to quickly to release the drug is considered incorrect.

Appellant argues that Tran does not disclose that the biodegradable material is within the graft of Tran. In response, the Examiner contends that this fact necessarily flows from the reference that teaches applying an aqueous collagen solution to the graft (section 2 on page 375). The Examiner posits that this would inherently get the collagen into the graft pores. Furthermore, Tran discloses that the collagen is

incorporated into the PTFE grafts (section 6 on page 376). For these reason, Appellant's arguments are considered unpersuasive.

Issue 5

In response to Appellant's arguments against Okita individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, Appellant traverses Okita as having no biodegradable composition. However, Okita was used as a teaching reference for the substrate and not for its coating composition.

Issue 6

Appellant traverses the rejection by stating that Okita teaches against cellular attachment. This is not true. In fact, one requirement of Okita is to allow fibroblast (i.e. cellular) entry into the graft structure; see column 11, lines 9-30.

Further, Appellant traverses the combination of Hoffman a fabric graft with Okita an expanded PTFE grafts because of their different pores sizes and structures. However, Okita provides a nexus between the two in the same passage; see column 11, lines 20-30. Furthermore, the motivation to combine these two references is clearly present since both desire to reduce or prevent blood leakage.

For these reasons, the Examiner posits that the rejection should be affirmed.

Issue 7

Appellant traverses the Alonso rejection by referring back to the arguments set forth in the Hoffman rejection. Similarly, the Examiner refers back to his rationale.

In addition, the Examiner would like to reiterate that cellular attachment is a naturally occurring process which Okita teaches the advantage of. For this reason, the argument that Okita does not desire cellular attachment is considered unpersuasive. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

pbp
March 11, 2002

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